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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,033	09/15/2003	Diane Taylor	07254-061003	2759

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FISH & RICHARDSON, PC
12390 EL CAMINO REAL
SAN DIEGO, CA 92130-2081

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,033	Applicant(s) TAYLOR ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 55-70 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/03</u> . | 6) <input type="checkbox"/> Other: ____. |

500

Art Unit: 1652

DETAILED ACTION

1. Claims 55-70 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 55, 59, 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Each of the claims recite the phrase "for sufficient time and under conditions such that a blood type antigen is produced" which is vague and indefinite. The metes and bounds are not clear since it is uncertain what amount of time is involved and what types of conditions are encompassed.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 55-57, 59-61, 63-65, 67-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1652

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

"Eli Lilly explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The claims are drawn to methods (claims 55-57 and 63-65) and a system (claims 67-69) comprising the use of a genus of alpha-1,2-fucosyltransferases or bioactive fragments thereof, a genus of polynucleotides encoding alpha-1,2-fucosyltransferases or bioactive fragments thereof, a genus of substrates for alpha-1,2-fucosyltransferase or bioactive fragments thereof, and a genus of blood type antigens.

The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid and nucleotide sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses a method of using a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1 encoding an alpha-1,2-fucosyltransferase consisting of the amino acid sequence of SEQ ID NO: 2 to make type H blood antigen.

However, the recitation of the names of the chemical compounds of each genus (e.g., alpha-1,2-fucosyltransferases) does not define any structural features commonly possessed by each claimed genus that distinguish them from others. Furthermore, the specification does not describe and define any structural features commonly possessed by each claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a

Art Unit: 1652

precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of alpha-1,2-fucosyltransferases or bioactive fragments thereof, a genus of polynucleotides encoding alpha-1,2-fucosyltransferases or bioactive fragments thereof, a genus of substrates for alpha-1,2-fucosyltransferase or bioactive fragments thereof, and a genus of blood type antigens.

6. Claims 55-57, 59-61, 63-65, 67-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for making Lewis Y, H type 1 antigen, or Lewis b comprising contacting Lewis X, type 1 acceptor, or Lewis a with an alpha-1,2-fucosyltransferase consisting of the amino acid sequence of SEQ ID NO: 2; does not reasonably provide enablement for any method or system for making any or all types of blood type antigens comprising contacting any alpha-1,2-fucosyltransferases or bioactive fragments including variants, mutants, and recombinants thereof with any substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method or system for making any or all types of blood type antigens comprising contacting any alpha-1,2-fucosyltransferases or

Art Unit: 1652

bioactive fragments including variants, mutants, and recombinants thereof with any substrate. The specification teaches a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1 encoding an alpha-1,2-fucosyltransferase consisting of the amino acid sequence of SEQ ID NO: 2; and a method to make Lewis Y, H type 1 antigen, or Lewis b comprising contacting Lewis X, type 1 acceptor, or Lewis a with said alpha-1,2-fucosyltransferase consisting of the amino acid sequence of SEQ ID NO: 2.

However, the specification does not provide guidance, prediction, and working examples for any method for making any or all types of blood type antigens comprising contacting any alpha-1,2-fucosyltransferases or bioactive fragments including variants, mutants, and recombinants thereof with any substrate.

Thus, an undue amount of trial and error experimentation must be preformed to make these bioactive enzyme fragments, variants, mutants, and recombinants thereof. Such experimentation entails searching and screening for specific mutations to make in the alpha-1,2-fucosyltransferase of SEQ ID NO: 2 (e.g., amino acid insertion, deletions, addition, substitution, and combinations thereof) without affecting alpha-1,2-fucosyltransferase activity. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 55-57, 59-61, 63-65, 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe (US Patent 5,595,900, published 01/21/1997).

Claims 55-57, 59-61, 63-65, 67-69 are drawn to a method for producing any blood type antigen comprising contacting any alpha-1,2-fucosyltransferase polypeptide or bioactive

Art Unit: 1652

fragment thereof with any substrate for any sufficient time and any conditions such that any blood type antigen is produced.

Lowe teach a method comprising contacting mH-12 host cells transformed with a polynucleotide encoding a human alpha-1,2-fucosyltransferase with H type 1 and H type 2 acceptors and chromatographic purification of the produced blood type antigens H type 1 and H type 2 (see entire patent especially (column 68, line 54 to column 69, line 22)). Since the above claims are drawn to any method of using any alpha-1,2-fucosyltransferase, then the method taught by Lowe anticipates the claims.

No patentable weight is given to the preamble of each of the process claims since it merely recites the purpose of the process. Because the process steps taught by Lowe are the same as the process steps of the claims, then the teachings of Lowe anticipate the claimed invention. Furthermore, the Examiner takes the position that Lowe teaches a system for producing blood type antigens as claimed since Lowe teaches each of the components of the claimed system: a transformed host cell expressing an alpha-1,2-fucosyltransferase (mH-12 host cells), contacting the host with substrates (H type 1 and H type 2 acceptors), and recovery of the produced blood type antigens H type 1 and H type 2. Thus, the reference teachings anticipate the claimed invention.

Conclusion

9. No claims are allowable.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1652

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L. Fronda
Patent Examiner
Art Unit 1652



Manjunath Rao
Primary Patent Examiner
Art Unit 1652